Randomization Eligibility Form Instructions
REL Version C: 05/20/2004
QxQ Date: 05/20/2004

I. GENERAL INSTRUCTIONS

The Randomization Visit Form: Eligibility (REL) is used to verify eligibility criteria before randomization so that randomization may occur. Especially important are any changes in renal graft function, documented decline in creatinine-based GFR eligibility, and interim vitamin supplement use. For further information on the randomization process, refer to Chapter 4 of the FAVORIT Manual of Procedures.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

It is important that this form be entered into the DMS WHILE THE PARTICIPANT IS PRESENT since the DMS will provide a study vitamin bottle code that is needed in order to dispense the vitamins to the participant.

II. SPECIFIC INSTRUCTION

A. Eligibility Criteria

1. The DMS will indicate if the total homocysteine level is above the FAVORIT eligibility cut point or not. This is indicated as "Yes" or "No". If "No" then the participant is not eligible; go to item 22. If the response is missing in the DMS, then the value has not yet been imported to the DMS from a filed received from the DCC.

2. The DMS will also display the creatinine clearance eligibility; indicated as "Yes" or "No". If "No" then the participant is not eligible; go to item 22. If the response is missing in the DMS, then the value has not yet been imported to the DMS from a filed received from the DCC.

3. Record "Yes" if the participant is currently between 35 and 75 years of age. At the time of randomization, the participant must be 35-75 years old. If the participant is currently younger than 35 years of age or older than 75 years of age record "No" and the participant is ineligible for the study; go to item 22.

4. Determine whether 6 months or longer have elapsed since the participant's current kidney graft was performed. If 6 or more months have elapsed record "Yes" then continue to the next item. If not, record "No" and the participant is ineligible for the study; go to item 22.

5. Record whether the patient has had any transplants other than kidney, kidney-pancreas or bone marrow. If 'Yes', the patient is not eligible for FAVORIT, go to item 22.

6. If the participant is currently (over the past month) using any vitamin supplements containing folic acid (folate), B6 or B12 record "Yes", the participant is ineligible; go to item 22. If the participant does not know if his or her vitamin supplement contains the specific vitamins of interest, ask for more information on the supplement. If it is determined that they contain no folic acid (folate) B6 or B12 record "No", then continue to next item.

7. Verify if a participant has a condition that will affect their 2-year survivability. If the participant has a condition, but it will not affect the participant's 2-year survivability then indicate "No".

    a. If the participant has cancer that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 22. Otherwise, record "No" and continue to the next item.

    b. If the participant has end stage congestive heart failure or cardiomyopathy that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 22. Otherwise, record "No" and continue to the next item.

    c. If the participant has end stage liver disease that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 22. Otherwise, record "No" and continue to the next item.

    d. If the participant has severe pulmonary disease that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 22 otherwise, record "No" and continue to the next item.

    e. If the participant has progressive HIV that is thought to affects his or her survivability over the next 2 years record "Yes", the participant is not eligible for FAVORIT, go to item 22. Otherwise, record "No" and continue to the next item.

    f. If the participant has a chronic wasting illness that was not listed in 7a – e that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 22. Otherwise, record "No" and continue to the next item.

8. Indicate if the participant is Male or Female. If Male record "M", go to item 12. If Female, record "F" and continue to the next item, Female Exclusion Criteria.

9. Female Exclusion Criteria:

    a. Record "Yes" if the participant is currently pregnant; this participant is ineligible for FAVORIT, go to item 22. If the participant is not pregnant, record "No", continue to the next item.

b. Record “Yes” if the participant is currently lactating; this participant is ineligible for FAVORIT, go to item 22. If the participant is not lactating, record “No”, continue to the next item.

10. Record “Yes” if the participant is of childbearing potential and continue to the next item. If she is not of childbearing potential record “No”, go to item 11. If the participant has had a partial hysterectomy or a total hysterectomy record "No" and go to item 11. Partial hysterectomy refers to removal of just the upper portion of the uterus, leaving the one or both ovaries and fallopian tubes intact. If the participant has reached menopause (i.e., no menstrual periods in the past 12 months), then record “No” for not being of childbearing potential.

11. Record “Yes” if the participant is currently using a FAVORIT study-accepted method of birth control and continue to the next item. If she is not using a study-accepted method of birth control record “No”, the participant is ineligible for FAVORIT, go to item 22.

    Study-accepted methods of birth control are:

    1) Oral contraceptives
    2) Tubal ligation
    3) Intrauterine device
    4) Depo-Provera
    5) Norplant

12. If a participant has a condition that will affect the participant’s ability to reliably participate in the study (e.g., make scheduled appointments, give informed consent, take the study vitamin regularly) record “Yes”. If the participant has a condition, but it will not affect the participant’s ability to participate in the study then indicate “No”.

    a. If the participant has refractory depression that will prevent the participant from participating in the study reliably, record “Yes” and go to item 22; the participant is not eligible for FAVORIT. Otherwise, record “No” and continue to the next item.

    b. If the participant has severe cognitive impairment that will prevent the participant from participating in the study reliably, record “Yes” and go to item 22; the participant is not eligible for FAVORIT. Otherwise, record “No” and continue to the next item.

    c. If the participant has alcoholism or another substance abuse problem that will prevent the participant from participating in the study reliably, record “Yes” and go to item 22; the participant is not eligible for FAVORIT. Otherwise, record “No” and continue to the next item.

13. If the participant is currently participating in another study that specifically involves cardiovascular disease risk factor management, record “Yes” and go to item 22; the participant is not eligible for FAVORIT. If the participant is currently participating in a study that does not involve CVD risk factors or the participant is not currently participating in another study, then record “No” and continue to the next item.

14. If the participant experienced a myocardial infarction (MI), stroke, percutaneous revascularization procedure (i.e., coronary cerebrovascular, or lower extremity), or lower extremity amputation within the past **3 months** of the current date, record "Yes" and go to item 22; the participant is ineligible for the study. If the participant experienced any of the conditions **more** than 3 months prior to the current date or the participant has not experienced any of the conditions ever, record "No" and continue to the next item.

15. If the participant had a coronary artery bypass graft, abdominal aortic aneurysm repair or carotid endarterectomy within the **past 6 months**, record "Yes" and go to item 22; the participant is ineligible for the study. If the participant had any of the operations **more** than 6 months prior to the current date or the participant has not had either of the operations performed ever, record "No" and continue to the next item.

16. If the participant has been hospitalized for renal graft dysfunction, or had renal graft deterioration, record "Yes" and go to item 22; the participant is not eligible for FAVORIT. Otherwise, record "No", continue to next item.

17. If the participant has returned to dialysis dependence, record "Yes" and go to item 22; the participant is not eligible for FAVORIT. Otherwise, record "No", continue to next item.

B. Randomization

18. At this time, if a paper form is being used, it will need to be entered into the DMS. If the participant has met all inclusion and exclusion criteria, and is ready to be randomized, record the date. Record the date of randomization in standard U.S. month/day/year format. For example, July 10, 2002 is recorded as 07/10/2002. The DMS will check this date again the computer date.

19. If the DMS is being used, a "Yes" response to this item triggers the computerized eligibility check. If the participant is eligible, he/she will be randomized as indicated through a bottle code displayed in item 21. Otherwise record "No", go to item 22.

20. Confirm the date of randomization and the reason for the discrepancy in dates.

    a. Record the correct date of randomization in standard U.S. month/day/year format. The DMS will check this date against the computer date if the dates match skip to item 20c. If they do not go to item 20b.

    b. If there is a difference between the dates in items 20a and the computer date, explain the difference. Contact the DCC immediately and they will assist you in devising an appropriate explanation.

    c. Enter "Yes" if you would like to randomize this patient. This will triggers the computerized eligibility check. If the participant is eligible, he/she will be randomized as indicated through a bottle code displayed in item 21. Otherwise record "No", go to item 22.

21. If a paper form is being used and the DMS randomized the participant, record the 2-digit bottle code assigned by the DMS. This will be the bottle code the participant will use throughout the study. This code also will need to be recorded on the Vitamin Distribution Log (VDL).

    Since the randomization procedure requires that the eligibility data be entered on the clinical center microcomputer (PC) before obtaining a treatment assignment, a backup procedure is necessary for cases in which the clinical center PC is unusable. In this situation refer to the Manual of Procedures Chapter 4, Randomization, section 4.5.3.

C. Administrative Information

22. Record the date that the randomization information was collected in U.S. order (month, day, year) using 2 digits each for the month and day, and 4 digits for the year.

23. Enter the data collector's initials using the 3 initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

If the participant is successfully randomized, distribute the study vitamins and complete the other forms that are required for the randomization visit. (Medication Listing Form, Medication Survey Form, Participant Update Form, Vitamin Distribution Log, Randomization Patient Characteristic Form and the Phlebotomy Forms (Collection and Processing & Inventory).

Randomization Eligibility Form Instructions
REL Version B: 11/04/2002
QxQ Date: 1/14/2003

I. GENERAL INSTRUCTIONS

The Randomization Visit Form: Eligibility (REL) is used to verify eligibility criteria before randomization so that randomization may occur. Especially important are any changes in renal graft function, documented decline in creatinine-based GFR eligibility, and interim vitamin supplement use. For further information on the randomization process, refer to Chapter 4 of the FAVORIT Manual of Procedures.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

It is important that this form be entered into the DMS while the participant is present since the DMS will provide a study vitamin bottle code that is needed in order to dispense the vitamins to the participant.

II. SPECIFIC INSTRUCTION

A. Demographics

1. Record the participant's date of birth, using the standard U.S. order (month/day/year). Code two digits for the month and day, and code four digits for the year. For example, July 10, 2002 is recorded as 07/10/2002.

2. a-e. For racial background, code Y or N to each race group listed. Multiple Yes's should be coded for mixed background.

3. For ethnic identification, code either H (Hispanic or Latino) or N (neither).

B. Eligibility Criteria

4. The DMS will indicate if the total homocysteine level is above the FAVORIT eligibility cut point or not. This is indicated as "Yes" or "No". If "No" then the participant is not eligible; go to item 24. If the response is missing in the DMS, then the value has not yet been imported to the DMS from a filed received from the DCC.

5. The DMS will also display the creatinine clearance eligibility; indicated as "Yes" or "No". If "No" then the participant is not eligible; go to item 24. If the response is missing in the

DMS, then the value has not yet been imported to the DMS from a filed received from the DCC.

6. Record "Yes" if the participant is currently between 35 and 75 years of age. At the time of randomization, the participant must be 35-75 years old. If the participant is currently younger than 35 years of age or older than 75 years of age record "No" and the participant is ineligible for the study; go to item 24.

7. Determine whether 6 months or longer have elapsed since the participant's current graft was performed.

    a. If 6 or more months have elapsed record "Yes" then continue to the next item. If not, record "No" and the participant is ineligible for the study; go to item 24

    b. If the current graft was performed 6 months ago or longer, indicate if the donor was a living related donor (record "L"), living unrelated donor (record "U") or a cadaver donor (record "C").

8. If the participant is currently (over the past month) using any vitamin supplements containing folic acid (folate), B6 or B12 record "Yes", the participant is ineligible; go to item 24. If the participant does not know if his or her vitamin supplement contains the specific vitamins of interest, ask for more information on the supplement. If it is determined that they contain no folic acid (folate) B6 or B12 record "No", then continue to next item.

9. Verify if a participant has a condition that will affect their 2-year survivability. If the participant has a condition, but it will not affect the participant's 2-year survivability then indicate "No".

    a. If the participant has cancer that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 24. Otherwise, record "No" and continue to the next item.

    b. If the participant has end stage congestive heart failure or cardiomyopathy that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 24. Otherwise, record "No" and continue to the next item.

    c. If the participant has end stage liver disease that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 24. Otherwise, record "No" and continue to the next item.

    d. If the participant has severe pulmonary disease that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 24 otherwise, record "No" and continue to the next item.

e. If the participant has progressive HIV that is thought to affects his or her survivability over the next 2 years record “Yes”, the participant is not eligible for FAVORIT, go to item 24. Otherwise, record “No” and continue to the next item.

f. If the participant has a chronic wasting illness that was not listed in 9a – e that is thought to affects his or her survivability over the next 2 years, record “Yes”, the participant is not eligible for FAVORIT, go to item 24. Otherwise, record “No” and continue to the next item.

10. Indicate if the participant is Male or Female. If Male record “M”, go to item 14. If Female, record “F” and continue to the next item, Female Exclusion Criteria.

11. Female Exclusion Criteria:

    a. Record “Yes” if the participant is currently pregnant; this participant is ineligible for FAVORIT, go to item 24. If the participant is not pregnant, record “No”, continue to the next item.

    b. Record “Yes” if the participant is currently lactating; this participant is ineligible for FAVORIT, go to item 24. If the participant is not lactating, record “No”, continue to the next item.

12. Record “Yes” if the participant is of childbearing potential and continue to the next item. If she is not of childbearing potential record “No”, go to item 14. If the participant has had a partial hysterectomy or a total hysterectomy record "No" and go to item 14. Partial hysterectomy refers to removal of just the upper portion of the uterus, leaving the one or both ovaries and fallopian tubes intact. If the participant has reached menopause (i.e., no menstrual periods in the past 12 months), then record “No” for not being of childbearing potential.

13. Record “Yes” if the participant is currently using a FAVORIT study-accepted method of birth control and continue to the next item. If she is not using a study-accepted method of birth control record “No”, the participant is ineligible for FAVORIT, go to item 24.

    Study-accepted methods of birth control are:

    1) Oral contraceptives
    2) Tubal ligation
    3) Intrauterine device
    4) Depo-Provera
    5) Norplant

14. If a participant has a condition that will affect the participant’s ability to reliably participate in the study (e.g., make scheduled appointments, give informed consent, take the study vitamin regularly) record “Yes”. If the participant has a condition, but it will not affect the participant’s ability to participate in the study then indicate “No”.

a. If the participant has refractory depression that will prevent the participant from participating in the study reliably, record "Yes" and go to item 24; the participant is not eligible for FAVORIT. Otherwise, record "No" and continue to the next item.

b. If the participant has severe cognitive impairment that will prevent the participant from participating in the study reliably, record "Yes" and go to item 24; the participant is not eligible for FAVORIT. Otherwise, record "No" and continue to the next item.

c. If the participant has alcoholism or another substance abuse problem that will prevent the participant from participating in the study reliably, record "Yes" and go to item 24; the participant is not eligible for FAVORIT. Otherwise, record "No" and continue to the next item.

15. If the participant is currently participating in another study that specifically involves cardiovascular disease risk factor management, record "Yes" and go to item 24; the participant is not eligible for FAVORIT. If the participant is currently participating in a study that does not involve CVD risk factors or the participant is not currently participating in another study, then record "No" and continue to the next item.

16. If the participant experienced a myocardial infarction (MI), stroke, percutaneous revascularization procedure (i.e., coronary cerebrovascular, or lower extremity), or lower extremity amputation within the past **3 months** of the current date, record "Yes" and go to item 24; the participant is ineligible for the study. If the participant experienced any of the conditions **more** than 3 months prior to the current date or the participant has not experienced any of the conditions ever, record "No" and continue to the next item

17. If the participant had a coronary artery bypass graft or abdominal aortic aneurysm repair within the **past 6 months**, record "Yes" and go to item 24; the participant is ineligible for the study. If the participant had any of the operations **more** than 6 months prior to the current date or the participant has not had either of the operations performed ever, record "No" and continue to the next item.

18. If the participant has been hospitalized for renal graft dysfunction, or had renal graft deterioration, record "Yes" and go to item 24; the participant is not eligible for FAVORIT. Otherwise, record "No", continue to next item.

19. If the participant has returned to dialysis dependence, record "Yes" and go to item 24; the participant is not eligible for FAVORIT. Otherwise, record "No", continue to next item.

C. Randomization

20. At this time, if a paper form is being used, it will need to be entered into the DMS. If the participant has met all inclusion and exclusion criteria, and is ready to be randomized, record the date. Record the date of randomization in standard U.S. month/day/year format. For example, July 10, 2002 is recorded as 07/10/2002. The DMS will check this date again the computer date. Iif the dates match then go to item 21. If they do not skip to item 22a.

21. If the DMS is being used, a "Yes" response to this item triggers the computerized eligibility check. If the participant is eligible, he/she will be randomized as indicated through a bottle code displayed in item 23. Otherwise record "No", go to item 24.

22. Confirm the date of randomization and the reason for the discrepancy in dates.

    a. Record the correct date of randomization in standard U.S. month/day/year format. The DMS will check this date against the computer date if the dates match skip to item 22c. If they do not go to item 22b.

    b. If there is a difference between the dates in items 22b and the computer date, explain the difference. Contact the DCC immediately and they will assist you in devising an appropriate explanation.

    c. Enter "Yes" if you would like to randomize this patient. This will triggers the computerized eligibility check. If the participant is eligible, he/she will be randomized as indicated through a bottle code displayed in item 23. Otherwise record "No", go to item 24.

23. If a paper form is being used and the DMS randomized the participant, record the 2-digit bottle code assigned by the DMS. This will be the bottle code the participant will use throughout the study. This code also will need to be recorded on the Vitamin Distribution Log (VDL).

    Since the randomization procedure requires that the eligibility data be entered on the clinical center microcomputer (PC) before obtaining a treatment assignment, a backup procedure is necessary for cases in which the clinical center PC is unusable. In this situation refer to the Manual of Procedures Chapter 4, Randomization, section 4.5.3.

D. Administrative Information

24. Record the date that the randomization information was collected in U.S. order (month, day, year) using 2 digits each for the month and day, and 4 digits for the year.

25. Enter the data collector's initials using the 3 initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

If the participant is successfully randomized, distribute the study vitamins and complete the other forms that are required for the randomization visit. (Medication Listing Form, Medication Survey Form, Participant Update Form, Vitamin Distribution Log, Randomization Patient Characteristic Form and the Phlebotomy Forms (Collection and Processing & Inventory).

Randomization Eligibility Form Instructions
REL Version A: 2/18/2002
QxQ Date: 6/10/2002

I. GENERAL INSTRUCTIONS

The Randomization Visit Form: Eligibility (REL) is used to verify eligibility criteria before randomization so that randomization may occur. Especially important are any changes in renal graft function, documented decline in creatinine-based GFR eligibility, and interim vitamin supplement use. For further information on the randomization process, refer to Chapter 4 of the FAVORIT Manual of Procedures.

Interviewers must be familiar with and understand chapter 14: Administrative Procedures, in the Manual of Procedures, prior to completing this form. The form header information (ID, Contact Occasion, Sequence Number, Name and Initials) is completed as described in that document.

It is important that this form be entered into the DMS while the participant is present since the DMS will provide a study vitamin bottle code that is needed in order to dispense the vitamins to the participant.

II. SPECIFIC INSTRUCTION

A. Demographics

1. Record the participant's date of birth, using the standard U.S. order (month/day/year). Code two digits for the month and day, and code four digits for the year. For example, July 10, 2002 is recorded as 07/10/2002.

2. a-e. For racial background, code Y or N to each race group listed. Multiple Yes's should be coded for mixed background.

3. For ethnic identification, code either H (Hispanic or Latino) or N (neither).

B. Eligibility Criteria

4. The DMS will indicate if the total homocysteine level is above the FAVORIT eligibility cut point or not. This is indicated as "Yes" or "No". If "No" then the participant is not eligible; go to item 25. If the response is missing in the DMS, then the value has not yet been imported to the DMS from a filed received from the DCC.

5. The DMS will also display the creatinine clearance eligibility; indicated as "Yes" or "No". If "No" then the participant is not eligible; go to item 25. If the response is

missing in the DMS, then the value has not yet been imported to the DMS from a filed received from the DCC.

6. Record "Yes" if the participant is currently between 35 and 75 years of age. At the time of randomization, the participant must be 35-75 years old. If the participant is currently younger than 35 years of age or older than 75 years of age record "No" and the participant is ineligible for the study; go to item 25.

7. Determine whether 6 months or longer have elapsed since the participant's current graft was performed.

    a. If 6 or more months have elapsed record "Yes" then continue to the next item. If not, record "No" and the participant is ineligible for the study; go to item 25

    b. If the current graft was performed 6 months ago or longer, indicate if the donor was a living related donor (record "L") or a cadaver donor (record "C").

8. If the participant is currently (over the past month) using any vitamin supplements containing folic acid (folate), B6 or B12 record "Yes", the participant is ineligible; go to item 25. If the participant does not know if his or her vitamin supplement contains the specific vitamins of interest, ask for more information on the supplement. If it is determined that they contain no folic acid (folate) B6 or B12 record "No", then continue to next item.

9. Verify if a participant has a condition that will affect their 2-year survivability. If the participant has a condition, but it will not affect the participant's 2-year survivability then indicate "No".

    a. If the participant has cancer that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 25. Otherwise, record "No" and continue to the next item.

    b. If the participant has end stage congestive heart failure or cardiomyopathy that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 25. Otherwise, record "No" and continue to the next item.

    c. If the participant has end stage liver disease that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 25. Otherwise, record "No" and continue to the next item.

    d. If the participant has severe pulmonary disease that is thought to affects his or her survivability over the next 2 years, record "Yes", the participant is not eligible for FAVORIT, go to item 25 otherwise, record "No" and continue to the next item.

e. If the participant has progressive HIV that is thought to affects his or her survivability over the next 2 years record “Yes”, the participant is not eligible for FAVORIT, go to item 25. Otherwise, record “No” and continue to the next item.

f. If the participant has a chronic wasting illness that was not listed in 9a – e that is thought to affects his or her survivability over the next 2 years, record “Yes”, the participant is not eligible for FAVORIT, go to item 25. Otherwise, record “No” and continue to the next item.

10. Indicate if the participant is Male or Female. If Male record “M”, go to item 14. If Female, record “F” and continue to the next item, Female Exclusion Criteria.

11. Female Exclusion Criteria:

    a. Record “Yes” if the participant is currently pregnant; this participant is ineligible for FAVORIT, go to item 25. If the participant is not pregnant, record “No”, continue to the next item.

    b. Record “Yes” if the participant is currently lactating; this participant is ineligible for FAVORIT, go to item 25. If the participant is not lactating, record “No”, continue to the next item.

12. Record “Yes” if the participant is of childbearing potential and continue to the next item. If she is not of childbearing potential record “No”, go to item 14. If the participant has had a partial hysterectomy or a total hysterectomy record "No" and go to item 14. Partial hysterectomy refers to removal of just the upper portion of the uterus, leaving the one or both ovaries and fallopian tubes intact. If the participant has reached menopause (i.e., no menstrual periods in the past 12 months), then record “No” for not being of childbearing potential.

13. Record “Yes” if the participant is currently using a FAVORIT study-accepted method of birth control and continue to the next item. If she is not using a study-accepted method of birth control record “No”, the participant is ineligible for FAVORIT, go to item 25.

    Study-accepted methods of birth control are:

    1) Oral contraceptives
    2) Tubal ligation
    3) Intrauterine device
    4) Depo-Provera
    5) Norplant

14. If a participant has a condition that will affect the participant’s ability to reliably participate in the study (e.g., make scheduled appointments, give informed consent, take the study vitamin regularly) record “Yes”. If the participant has a condition, but it will not affect the participant’s ability to participate in the study then indicate “No”.

a. If the participant has refractory depression that will prevent the participant from participating in the study reliably, record "Yes" and go to item 25; the participant is not eligible for FAVORIT. Otherwise, record "No" and continue to the next item.

b. If the participant has severe cognitive impairment that will prevent the participant from participating in the study reliably, record "Yes" and go to item 25; the participant is not eligible for FAVORIT. Otherwise, record "No" and continue to the next item.

c. If the participant has alcoholism or another substance abuse problem that will prevent the participant from participating in the study reliably, record "Yes" and go to item 25; the participant is not eligible for FAVORIT. Otherwise, record "No" and continue to the next item.

15. If the participant is currently participating in another study that specifically involves cardiovascular disease risk factor management, record "Yes" and go to item 25; the participant is not eligible for FAVORIT. If the participant is currently participating in a study that does not involve CVD risk factors or the participant is not currently participating in another study, then record "No" and continue to the next item.

16. If the participant experienced a myocardial infarction (MI), stroke, percutaneous revascularization procedure (i.e., coronary cerebrovascular, or lower extremity), or lower extremity amputation within the past **3 months** of the current date, record "Yes" and go to item 25; the participant is ineligible for the study.. If the participant experienced any of the conditions **more** than 3 months prior to the current date or the participant has not experienced any of the conditions ever, record "No" and continue to the next item

17. If the participant had a coronary artery bypass graft or abdominal aortic aneurysm repair within the **past 6 months**, record "Yes" and go to item 25; the participant is ineligible for the study. If the participant had any of the operations **more** than 6 months prior to the current date or the participant has not had either of the operations performed ever, record "No" and continue to the next item.

18. If the participant has been hospitalized for renal graft dysfunction, or had renal graft deterioration, record "Yes" and go to item 25; the participant is not eligible for FAVORIT. Otherwise, record "No", continue to next item.

19. If the participant has returned to dialysis dependence, record "Yes" and go to item 25; the participant is not eligible for FAVORIT. Otherwise, record "No", continue to next item.

C. Randomization

20. If the participant has met all inclusion and exclusion criteria, and is ready to be randomized, record "Yes". At this time, if a paper form is being used, it will need to be entered into the DMS. If the DMS is being used, a "Yes" response to item 20 triggers the computerized eligibility check. If the participant is eligible, he/she will be randomized as

indicated through a bottle code displayed in item 21. Otherwise record "No", go to item 25.

21. If a paper form is being used and the DMS randomized the participant, record the 2-digit bottle code assigned by the DMS. This will be the bottle code the participant will use throughout the study. This code also will need to be recorded on the Vitamin Distribution Log (VDL).

    Since the randomization procedure requires that the eligibility data be entered on the clinical center microcomputer (PC) before obtaining a treatment assignment, a backup procedure is necessary for cases in which the clinical center PC is unusable. In this situation refer to the Manual of Procedures Chapter 4, Randomization, section 4.5.3.

22. If a paper form is being used and the DMS randomized the participant, record the date of randomization as determined by the DMS.

23. If the date in item 22 is the date the participant was randomized (i.e., date the bottle code is first assigned), record "Yes" and go to item 25. Otherwise record "No" and contact the DCC immediately.

24 Record the correct date of randomization and the reason for the discrepancy in dates.

    a. Record the correct date of randomization in standard U.S. month/day/year format. For example, July 10, 2002 is recorded as 07/10/2002.

    b. If there is a difference between the dates in items 22 and 24, explain the difference. The DCC will assist you in devising an appropriate explanation.

D. Administrative Information

25. Record the date that the randomization information was collected in U.S. order (month, day, year) using 2 digits each for the month and day, and 4 digits for the year.

26. Enter the data collector's initials using the 3 initials of the person completing this form. If he/she only has two initials, then record the 1st name initial in the first box, the last name initial in the 2nd box and leave the third box blank.

If the participant is successfully randomized, distribute the study vitamins and complete the other forms that are required for the randomization visit. (Medication Listing Form, Medication Survey Form, Participant Update Form, Vitamin Distribution Log, Randomization Patient Characteristic Form and the Phlebotomy Forms (Collection and Processing & Inventory).